

K102776

FEB 18 2011

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DATE PREPARED: February 2, 2011

TRADE OR PROPRIETARY NAME: e-DENT TEMPORARY RESIN and EXTRA-ORAL CURING SYSTEM

CLASSIFICATION NAME: Temporary Crown and Bridge Resin, per 21 CFR 872.3770

PREDICATE DEVICE: K070991, VITA CAD TEMP, Temporary Crown and Bridge Resin, per 21 CFR 872.3770

This summary includes only information that is also covered in the body of this 510(k) document, does not contain any puffery or unsubstantiated labeling claims, does not contain any raw data, i.e., contains only summary data, and does not contain any patient identification information. Confidential formulas are included.

DEVICE DESCRIPTION: e-DENT TEMPORARY RESIN is a radiopaque, filled, resin-based temporary dental restorative composite. In general terms, the device is a typical, high quality, esthetic dental composite, composed of difunctional acrylic monomers and silaceous fillers. The product will polymerize on exposure to high-intensity incandescent illumination, yielding a hard, esthetic, temporary restoration that mimics natural tooth structure.

e-DENT TEMPORARY RESIN is intended to be fabricated in a laboratory-based, additive, Computer-Aided Manufacturing (CAM) and curing system, such as the EXTRA-ORAL CURING SYSTEM disclosed in this submission. The curing system consists of two pieces of equipment used to manufacture photocurable dental resin devices in a dental laboratory, using accompanying software to form and cure the devices.

INTENDED USE: The e-DENT TEMPORARY resin is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment.

TECHNOLOGICAL CHARACTERISTICS vs. the predicate device: The e-DENT TEMPORARY RESIN is essentially identical to the predicate device. Both materials use Computer Aided Design files for their manufacture into temporary crowns or bridges in a laboratory. Clinical use of e-DENT TEMPORARY RESIN is substantially equivalent to VITA CAD TEMP.

The VITA CAD TEMP material is a high molecular weight acrylate polymer with microfillers that were previously cured. The VITA CAD TEMP material is machined to its final shape using diamond instruments on a CAM device, which is known as subtractive manufacturing. By contrast, the e-DENT TEMPORARY RESIN uses additive manufacturing; that is a CAM system cures the resin in 0.1 mm layers to gradually form the precise shape for the crown or bridge.

OTHER: The e-DENT TEMPORARY RESIN was not evaluated for its specific biocompatibility because all components have been used in previously cleared resins manufactured by DeltaMed. The EXTRA-ORAL CURING SYSTEM was not evaluated for biocompatibility because no part of this equipment is used for patient contact.

We believe that the performance data provided herein support the safety and effectiveness of use of e-DENT TEMPORARY RESIN and EXTRA-ORAL CURING SYSTEM.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Emanuel Mesaric
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GERMANY

FEB 18 2011

Re: K102776

Trade/Device Names: e-Dent Temporary Resin and Extra-Oral Curing System
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Codes: EBG
Dated: February 3, 2011
Received: February 16, 2011

Dear Mr. Mesaric:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Mesaric

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102776

Device Name: e-DENT TEMPORARY RESIN and EXTRA-ORAL CURING SYSTEM

Indications For Use: e-DENT TEMPORARY resin is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of ~~Division of General and Diagnostic Devices~~ (ODE)
Page 1 of 1 Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Premarket Notification

DeltaMed GmbH
K102776: e-DENT TEMPORARY RESIN and EXTRA-ORAL AND CURING SYSTEM

510(k) Number: K102776
Page 17 of 51